UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DINA ANDREN and SIDNEY BLUDMAN, individually and on behalf of other members of the general public similarly situated,

Plaintiffs,

v.

ALERE, INC., a Delaware corporation ALERE HOME MONITORING, INC., a Delaware Corporation; ALERE SAN DIEGO, INC., a Delaware corporation,

Defendants.

CASE NO. 16cv1255-GPC(NLS)

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS WITH LEAVE TO AMEND

[Dkt. No. 11.]

Before the Court is Defendants' motion to dismiss the complaint. (Dkt. No. 11.) An opposition and reply were filed. (Dkt. Nos. 16, 17.) Based on the reasoning below, the Court GRANTS Defendants' motion to dismiss with leave to amend.

Background

On May 26, 2016, Plaintiffs Dina Andren ("Andren") and Sidney Bludman

("Bludman") filed a purported class action complaint alleging that Defendants Alere, Inc., Alere Home Monitoring, Inc. and Alere San Diego, Inc. ("Defendants") unlawfully, deceptively and misleadingly engaged in the manufacturing, marketing and sales of the INRatio products which include "INRatio PT/INR Monitors," "INRatio PT/INR Test Strips," "INRatio2 PT/INR Monitors" and "INRatio2 PT/INR Test Strips" (collectively, the "INRatio products"). (Dkt. No. 1, Compl.)

In the late 1990's Defendants' predecessor, HomoSense, Inc.[1], developed and manufactured the "INRatio products" which are electronic testing devices designed to assist patients who have been prescribed blood-thinners, such as warfarin, to monitor their blood clotting time at home. (Id. ¶¶ 2, 14, 20.) The INRatio monitor, paired with the INRatio test strips are known as the "INRatio testing kit" (Id. ¶ 21.) The ability to monitor and test their blood-clotting times and adjust patients' blood-thinner dosages is critical as an inappropriate amount of blood-thinners can result in serious bodily injury and death. (Id. ¶ 2.)

The International Normalized Ratio ("INR") is a standardized metric used to determine the relative speed at which blood clots in a patient's body. (Id. ¶ 17.) "A patient's INR is calculated by comparing a patient's prothrombin time (the speed at which the patient's blood clots) against the normal mean prothrombin time (the average speed for bloodclotting in the general population). The resulting contrast between a patient's prothrombin time and the normal mean prothrombin time is the patient's INR." (Id.) Doctors and patients use the INR to monitor the blood-clotting speed for patients who have been prescribed blood thinners to determine whether a patient should increase or decrease his/her dosage of blood thinners. (Id. ¶ 18.)

In October 2002, the FDA approved the INRatio testing kit for home use and sales began in 2003. (Id. ¶ 22.) The "INRatio2" testing kit was later developed and

[1]In August 2007, Alere, Inc. (then known as Inverness Medical Innovaction, Inc.) purchased HomoSense, Inc. (Dkt. No. 1, Compl. ¶ 14.) In 2008, HomoSense, Inc. transferred its operations to Alere, Inc's facility in San Diego, California. (Id.) In 2013, HomoSense, Inc.'s operations were merged into the Alere San Diego corporate entity. (Id.)

operated similarly to the INRatio testing kit. (Id. ¶ 23.)

Sometime immediately after the INRatio products became available to the public, Defendants received numerous complaints about the INRatio products' efficacy and accuracy. (Id. ¶ 26.) For example, some consumers found that the INR results they were getting when using the INRatio products differed from the results they obtained when they sent blood from the same samples to independent labs for testing. (Id.) The deviations between the INRatio products' test results and those of independent labs were "clinically significant." (Id.) Between 2002 and 2014, Defendants received over 18,000 complaints concerning malfunctions with the INRatio products, no less than 3 of which resulted in deaths. (Id. ¶ 28.)

In May 2005, after receiving numerous complaints about the INRatio products, the FDA conducted an inspection of Defendants' San Jose operations facility and following the inspection, the FDA sent a warning letter admonishing them for their failure to file Medical Device Reporting ("MDR") reports based on failing to report complaints about "discrepant lab results" and "generating clinically significant erroneous values." (Id. ¶¶ 29-33.) From May 15, 2006 through July 13, 2006, the FDA conducted another inspection of the San Jose facility and on November 29, 2006, the FDA sent Defendants another warning letter for numerous failure to comply with statutory regulations. (Id. ¶¶ 34, 35.)

On April 16, 2014, Defendants issued a voluntary "Class 1" recall notice for the INRatio2 test strips, citing the disparity between INR results obtained with the INRatio2 system versus significantly higher INR results when re-testing was performed by an independent laboratory. (Id. ¶ 38.) Defendants' recall notice requested that customers immediately cease using the INRatio2 PT/INR test strips and instead use alternate methods to perform INR testing. (Id.) Despite the recall, Defendants did not reimburse consumers for the purchase of these dangerous devices. (Id.) On December 5, 2014, Defendants issued a voluntary recall letter for the INRatio PT/INR Monitor and INRatio2 PT/INR Monitor, as well as the INRatio PT/INR Test Strips. The letter

stated, "[i]n certain cases an INRatio PT/INR Testing kit may provide an INR result that is significantly lower than a result obtained using a laboratory INR system." (Id. ¶ 40.) The letter also instructed customers, inter alia, to discuss the contents of the letter with their doctors and "arrange with your doctor to have your INR measured using a laboratory method." (Id.)

Despite receiving numerous complaints from users and multiple warning letters from the FDA, notifying them that the results produced by the INRatio products differed from those produced by independent laboratories, Defendants continued selling the INRatio products and marketed and advertised them as "accurate," "convenient," "effective," "reliable," "optimal" and "safe. (Id. ¶ 3.) As a result, due to the erroneous results produced by the products, patients have been misled and have caused them to improperly adjust their blood-thinner dosages increasing the risk and likelihood of serious bodily injury or death. (Id. ¶ 4.)

Plaintiffs allege that Defendants misrepresented in its marketing advertising and promotional materials that the INRatio products were "accurate" "convenient," "effective," "reliable," "optimal," and "safe" and Defendants made further misrepresentations to consumers by omitting material information, particularly by failing to disclose that the INRatio products produce false and misleading results, from the packaging and marketing materials of the INRatio testing kit. (Id. ¶ 21.)

Plaintiff Dina Andren suffers from a medical condition that requires her to regularly take warfarin. (Id. ¶ 53.) As a result, Andren closely monitors her INR with an INRatio2 PT/INR testing kit she bought from a pharmacy on April 30, 2015 for $375 and which requires her to buy numerous boxes of replacement INRatio test strips, that range in price from $240-285 per box, to continue monitoring the INR. (Id. ¶¶ 53-55.) "When purchasing her INRatio products, she relied on Alere's representations that the products were accurate, convenient, effective, reliable, optimal and safe." (Id. ¶ 56.) Were it not for these representations or had she known that Alere was omitting that it knew its products produced erroneous INR results, Andren would not have purchased

or used the INRatio products. (Id.)

On the morning of May 24, 2015, Andren tested her INR using her INRatio2 testing kit. (Id. ¶ 57.) The test results indicated an INR of 2.7 and believing her INR was above 2.5, Plaintiff Andren did not take Lovenox. (Id.) Later that day, Plaintiff Andren was rushed to the hospital where doctors determined she had suffered a stroke. (Id. ¶ 58.) Following her stroke, Andren continued using her INRatio2 and accompanying test strips to closely monitor her INR and adjust her warfarin dosage accordingly. (Id. ¶ 59.) In July of 2015, after having carefully monitored and regulated her INR with the INRatio 2 testing kit for over a month following her stroke, Andren suffered a Transient Ischemic Attack ("TIA"), otherwise known as a "mini-stroke." (Id. ¶ 60.) When Andren returned home, she continued to use her INRatio2 testing kit to monitor her INR and had another TIA in March 2016. (Id. ¶¶ 61, 62.) While at the hospital, Andren was informed, for the first time, that her INRatio2 testing kit had been the subject of a Class 1 recall. (Id. ¶ 63)

Plaintiff Sidney Bludman has suffered from a medical condition that requires him to regularly take warfarin for 28 years. (Id. ¶ 65.) For approximately 26 years, Bludman would have his INR tested once a month in a laboratory. (Id. ¶ 66.) For all 26 years, his INR remained fairly consistent and required very infrequent minor adjustments of his warfarin dosage. (Id.)

Bludman began using an INRatio2 PT/INR testing kit to regularly monitor his INR at home in 2013 and he was required to purchase boxes of replacement INRatio2 test strips in order to continue with his periodic INR testing and each contained 24 replacement test trips that costs about $120. (Id. ¶¶ 67, 68.) "In using the INRatio products, Bludman relied on Alere's representations that the products were accurate, convenient, effective, reliable, optimal and safe." (Id. ¶ 69.) Were it not for these representations, and the omission of material information that INRatio products produced erroneous results, Bludman would not have purchased or used the INRatio products. (Id.)

In February of 2016, his INR, tested on his INRatio2 testing kit, became exceedingly high and based on the high INR, Bludman reduced his warfarin dosage which caused him to suffer a TIA on February 10, 2016. (Id. ¶¶ 70, 71.) Upon returning home from the hospital, Bludman began monitoring his INR with his INRatio2 testing kit and compared those results with the results of blood tests conducted by a laboratory at his hospital. (Id. ¶ 72.) He found that his INR, as indicated by his INRatio2 testing kit, was consistently .4-.6 higher than his INR, as indicated by the results of the lab tests. (Id.) As a result of his TIA, Bludman is now at a higher risk for future ischemic attacks. (Id. ¶ 73.)

Plaintiff alleges four causes of action for violations of California's Consumers Legal Remedies Act ("CLRA"), California's Unfair Competition Law pursuant to California Business & Professions Code section 17200 *et seq*. ("UCL"), fraud and unjust enrichment. (Dkt. No. 1. Compl.) Defendants move to dismiss all four causes of action based on Plaintiffs' failure to satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b) for their allegations of material misrepresentations and fraudulent omissions.

A. Defendants' Request for Judicial Notice

In their opposition, Defendants request judicial notice of numerous documents arguing that either they are referenced in the Complaint or they are matters of public record and not subject to reasonable dispute. (Dkt. No. 11-1.) In response, Plaintiffs object as to Exhibit B, "Alere INRatio2 Self-Test User Guide", and Exhibit A, "FDA 501(k) Substantial Equivalence Determination Decision Summary" ("501(k) Summary"). (Dkt. No. 17.) Plaintiffs object because Defendants are not using the existence of these documents to attack the Complaint on its face but are relying on the contents of the documents to assert merits-based defenses to Plaintiffs' allegations. They also object because the User Guide is not authenticated. In reply, Defendants argue that these documents are proper for judicial notice.

As a general rule, "a district court may not consider any material beyond the

pleadings in ruling on a Rule 12(b)(6) motion." Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001). However, two exceptions exist where a district court may take consider "material which is properly submitted as part of the complaint" or if the documents are not attached to the complaint, they may be considered if the documents' "authenticity . . . is not contested" and "the plaintiff's complaint necessarily relies" on them. Id. (citations omitted). In addition, a court may take judicial notice of "matters of public record" under Federal Rule of Civil Procedure ("Rule") 201. Id. at 688-89. Under Rule 201, a court may not take judicial notice of a fact that is "subject to reasonable dispute." Fed. R. Evid. 201(b). If the contents of a matter of public record are in dispute, the court may take notice of the fact of the document at issue but not of the disputed information contained within. See Lee, 250 F.3d at 689-90.

Here, as to Exhibit B, the Complaint does not cite to or rely on the User Guide, the User Guide is not a matter of public record and Plaintiffs challenge its authenticity. Therefore, judicial notice of the User Guide is not proper and the Court DENIES Defendants' request for judicial notice as to Exhibit B. Furthermore, as Plaintiffs note and the Court agrees, Defendants ask the Court to consider documents outside the complaint and to rule on a factual issue not proper on a motion to dismiss. In their motion, Defendants seek dismissal of the complaint arguing that the User Guide provides sufficient disclosures concerning the INRatio products and that they did not omit material information. While Defendants argue that their disclosures were sufficient, such a ruling is not proper at the motion to dismiss stage.

As to Exhibit A, Plaintiffs argue that Defendants improperly cite to the contents of the 510(k) Summary asserting in their motion that "Patients can obtain these devices only with a prescription." (Dkt. No. 11, Ds' Mot. at 8.) Plaintiffs dispute that Alere INRatio2 PT/INR can be only be obtained with a prescription and state they allege, in their complaint, that Andren purchased the product from a pharmacy absent a prescription. (Dkt. No. 17 at 4.) Contrary to Plaintiffs' argument, the Complaint does not allege Andren purchased the INRatio2 PT/INR "absent a prescription." Despite

Plaintiffs' failure to assert that Andren purchased the product without a prescription, because Plaintiffs dispute their contents, the Court can only take judicial notice of the fact of the document and not the contents contained in the document. See Lee, 250 F.3d at 689-90. Accordingly, the Court DENIES Defendants' request for judicial notice of Exhibits A & B. The Court GRANTS Defendants' request for judicial notice of Exhibits C through G as they are matters of public record and are unopposed.

B. Legal Standard on Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure ("Rule") 12(b)(6) permits dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. See Balistreri v. Pacifica Police Dep't., 901 F.2d 696, 699 (9th Cir. 1990). Under Rule 8(a)(2), the plaintiff is required only to set forth a "short and plain statement of the claim showing that the pleader is entitled to relief," and "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint may survive a motion to dismiss only if, taking all well-pleaded factual allegations as true, it contains enough facts to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "In sum, for a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009) (quotations omitted). In reviewing a Rule 12(b)(6) motion, the Court accepts as true all facts alleged in the complaint, and draws all reasonable inferences in favor of

the plaintiff. al-Kidd v. Ashcroft, 580 F.3d 949, 956 (9th Cir. 2009).

Where a motion to dismiss is granted, "leave to amend should be granted 'unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.'" DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992) (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986)). In other words, where leave to amend would be futile, the Court may deny leave to amend. See Desoto, 957 F.2d at 658; Schreiber, 806 F.2d at 1401.

C. Legal Standard as to Federal Rule of Civil Procedure 9(b)

Where a plaintiff alleges fraud in the complaint, Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A party must set forth "the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." Odom v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007) (internal quotation marks omitted). Rule 9(b) also applies to claims that are "grounded in fraud" or "sound in fraud." Vess v. Ciba-Geigy Corp., U.S.A., 317 F.3d 1097, 1103-04 (9th Cir. 2003). Asserting that the defendant "'knowingly and purposefully failed to disclose'" the alleged defect is subject to Rule 9(b), since that amounts to an allegation of knowledge of falsity and intent to defraud." Shin v. BMW of North America, No. CV 09-00395 AHM (AJWx), 2009 WL 2163509, at *4 (C.D. Cal. July 16, 2009).

Defendants argue that the complaint fails to meet the heightened pleading requirements under Rule 9(b) for failing to allege that they made any affirmative representations specifically to Plaintiffs, that Plaintiffs relied on any such misrepresentations or that Alere had any duty to disclose information not already disclosed by the Alere entities. Plaintiffs do not dispute that the heightened pleading requirement applies but argue that they have sufficiently alleged particularity as to the alleged affirmative misrepresentations and omissions.

Plaintiffs allege four causes of action for violations of the CLRA, the UCL, fraud, and unjust enrichment. (Dkt. No. 1. Compl.) All causes of action in the Complaint either allege fraud or sound in fraud where Plaintiffs' allegations are premised on a uniform course of fraudulent conduct, (Dkt. No. 1. Compl. ¶¶ 93, 94, 99 (CLRA), ¶¶ 104, 110 (UCL), ¶¶ 113-121 (fraud), and ¶ 125 (unjust enrichment)); therefore, all claims are subject to the heightened pleading standard of Rule 9(b). See Vess, 317 F.3d at 1103-04 (holding that when a plaintiff "allege[s] a unified course of fraudulent conduct and rely entirely on that course of conduct as the basis of a claim. . . the claim is said to be 'ground in fraud' or to 'sound in fraud,' and the pleading of that claim as a whole must satisfy the particularity requirement of Rule 9(b)."). The Ninth Circuit has held that claims of nondisclosure and omissions are subject to the pleading standard of Rule 9(b). Kearns v. Ford Motor Co., 567 F.3d 1120, 1126-27 (9th Cir. 2009) (applying Rule 9(b) to fraud claims under the CLRA and UCL).

All four causes of action are premised on material misrepresentations and fraudulent omissions; therefore, the Court looks at whether Plaintiffs have satisfied Rule 9(b) in asserting these allegations.

1. Material Misrepresentations

First, Defendants argue that Plaintiffs failed to allege they ever viewed or relied on a representation made by them. In responding, Plaintiffs assert that Defendants made material misrepresentations in their packaging, marketing, advertising and promotional materials where they claimed the INRatio products were "accurate" "convenient" "effective" "reliable" "optimal" and "safe" when in fact they were not. (Dkt. No. 1, Compl. ¶¶ 21, 24-27.) Plaintiffs also argue that they do not need to prove reliance as there is a presumption of reliance in a fraudulent omission case or misrepresentation case.[2]

[2]Plaintiffs' citation to cases pleading reliance in federal securities fraud under Rule 10b-5 case are not persuasive. See Binder v. Gillespie, 184 F.3d 1059, 1063-64 (9th Cir. 1999); Affiliated Ute Citizens v. United States, 406 U.S. 128, 153-54 (1972). In Mirkin, the California Supreme Court rejected the application of the Ute

A cause of action under UCL requires that plaintiff must plead reliance and it can do so without alleging that those misrepresentation were the "sole or even the decisive cause of the injury-producing conduct," In re Tobacco II Cases, 46 Cal. 4th 298, 328 (2009). However, where there are underlying allegations of fraud, where the claim is "grounded in fraud", Rule 9(b) applies to California's consumer protection statutes. Kearns, 567 F.3d at 1125. The pleading, as a whole, must comply with Rule 9(b). Id.

In Kearns, the plaintiff, alleged claims under the CLRA and UCL, for defendants' misrepresentations and fraud regarding its "certified pre owned" vehicle program. Id. at 1122. The Ninth Circuit upheld the district court's dismissal because the plaintiff failed to specify when he was exposed to the representations and which sales material he relied on in making his decision to buy the product. Id. at 1126 (concluding that plaintiff did not articulate the "who, what, when, where, and how of the misconduct alleged"). A party must set forth "the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." Odom v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007) (internal quotation marks omitted); Buckley v. Align Tech., Inc., No. 13cv2812-EJD, 2015 WL 5698751, at *3 (N.D. Cal. 2015) (plaintiff failed to identify any false or misleading statements made to her by Defendant.)

In addition,"Rule 9(b)'s particularity requirement can be satisfied by 'identifying or attaching representatives samples' if the alleged misrepresentations occur in printed form." Shields v. Alere Home Monitoring, Inc., No. C-15-2580 CRB, 2015 WL 7272672, at *6 (N.D. Cal. Nov. 18, 2015) (citations omitted). However, a plaintiff must specify what the misrepresentations stated, when he or she was exposed to the misrepresentation and which ones he or she found material. See Kearns, 567 F.3d at

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presumption of reliance, to California law. Mirkin, 5 Cal. 4th 1082, 1093 (1993) (the "body of law that has developed under Rule 10b-5 is not sufficiently analogous to the law of fraud to justify its importation into the latter."). The other district court cases cited by Plaintiffs are not applicable because those cases do not assert UCL or CLRA claims grounded in fraud. See Shin v. BMW of North America, No. CV 09-398, 2009 WL 2163509, at *4 (C.D. Cal. July 16, 2009); Delarosa v. Boiron, Inc., 275 F.R.D. 582, 586 (C.D. Cal. 2011).

1125-26.

The Complaint alleges that when Andren and Bludman purchased the INRatio2 PT/INR testing kits, they "relied on Alere's representations that the products were accurate, convenient, effective, reliable, optimal and safe." (Id. ¶¶ 56, 69.) These are merely general allegations that do not allege where Plaintiffs saw or heard the representations, such as through Defendants' marketing, advertising, promotional or packaging materials, and when they saw those representations. In addition, Plaintiffs, in the Complaint, insert a copy of a web page for the Alere INRatio2 PT/INR Monitoring System, (Dkt. No. 1, Compl. ¶ 25), concerning the alleged misrepresentations; however, again, Andren and Bludman do not allege that they ever saw or relied on this web page. Therefore, Plaintiffs cannot link their injuries to those alleged misrepresentations. The Complaint makes numerous allegations as to the alleged material misrepresentations in Defendants' marketing, advertising, promotional, and packaging[3] materials but do not specifically allege when and where Andren and Bludman saw the misrepresentations. Accordingly, the Court GRANTS Defendants' motion to dismiss all claims under Rule 9(b) premised on material misrepresentations.

2. Fraudulent Omissions

Next, Defendants argue that Plaintiffs have not alleged a duty to disclose the alleged fraudulently omitted facts. Plaintiffs contend that they have sufficiently alleged a duty to disclose.

"In order to state a claim of fraudulent omissions under the UCL/FAL, CLRA, or as a claim of common law fraud, a plaintiff must allege facts either showing that the alleged omissions are 'contrary to a representation actually made by the defendant, or showing an omission of a fact the defendant was obliged to disclose.'" Davidson v.

[3]The Complaint alleges misrepresentations were also made on the packaging. (Dkt. No. 1, Compl, ¶¶ 21, 24, 108, 119.) In their opposition, Plaintiffs discuss the package insert, the "User Guide", and state "as a matter of law, any disclosures made to Plaintiffs after they purchased the INRatio Products are irrelevant." (Dkt. No. 16 at 17.) It is not clear whether Plaintiffs are alleging reliance on the packaging or not.

Kimberly-Clark Corp., 76 F. Supp. 3d 964, 972 (N.D. Cal. 2014) (quoting Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 835 (2006)).

"The required elements for fraudulent concealment are (1) concealment or suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing or suppressing the fact; (4) the plaintiff was unaware of the fact and would not have acted as he or she did if he or she had known of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of the concealment or suppression of the fact." Graham v. Bank of America, N.A., 226 Cal. App. 4th 594, 606 (2014) (citation omitted).

The parties argue that there are four circumstances in which an obligation to disclose may arise "(1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material facts." LiMandri v. Judkins, 52 Cal. App. 4th 326, 336 (1997). The same duty to disclose also applies to UCL and CLRA causes of action. Baba v. Hewlett–Packard Co., No. C 09–05946 RS, 2010 WL 2486353, at *7 (N.D. Cal. June 16, 2010).

Defendants argue that Plaintiffs have not alleged a duty to disclose.[4] According to Plaintiffs, the Complaint alleges a duty based on Defendants' exclusive knowledge of material facts, that INRatio products produced false and erroneous results, not known to them and that Defendants actively concealed material facts from Plaintiffs. (Dkt. No. 1, Compl. ¶¶ 26-41.)

A defendant has exclusive knowledge giving rise to a duty to disclose when

[4]Defendants also argue that they did not fail to disclose the discrepant results of the INRatio products because the User Guide disclosed such information. Since the Court denied Defendants' request for judicial notice of the User Guide, Defendants' argument based on the User Guide is without merit.

"according to the complaint, [defendant] knew of this defect while plaintiffs did not, and, given the nature of the defect, it was difficult to discover." Collins v. eMachines, Inc., 202 Cal. App. 4th 249, 256 (2011); Falk v. General Motors Corp., 496 F. Supp. 2d 1088, 1096 (N.D. Cal. 2007) (a duty to disclose exists "when the defendant [s] had exclusive knowledge of material facts not known to plaintiff[s]."). "[G]eneralized allegations with respect to exclusive knowledge" are insufficient to defeat a dismissal motion. Hovsepian v. Apple, Inc., No. 08–5788 JF (PVT), 2009 WL 5069144, at *3 (N.D. Cal. Dec. 17, 2009).

Here, Plaintiff alleges that Defendants had exclusive knowledge of material facts and cites to paragraphs 26-37 of the Complaint. (Dkt. No. 16 at 15.) These paragraphs do not support the allegation that Defendants had exclusive knowledge. For example, the Complaint references a publication in 2007 where a study conducted testing on INR testing devices, and the INRatio products performed the worst, with results that deviated most significantly from the results obtained through an outside laboratory. (Dkt. No. 1, Compl. ¶ 27 & n. 4.) In addition, the Complaint references and attaches an FDA warning letter of 2005 posted on its website noting the discrepant values. (Dkt. No. 1, Compl. ¶ 30; Dkt. No. 1-2, Ex. A to Compl.) The Complaint also references and attaches recall letters dated April 16, 2014 and December 5, 2014 that were sent to consumers and healthcare professionals concerning the different test results between INRatio products and INR tested in a laboratory. (Dkt. No. 1-4, Ex. C to Compl; Dkt. No. 1-5, Ex. D to Compl.) These allegations demonstrate that the material facts were not within the exclusive knowledge of Defendants but available to the public. Plaintiffs' own allegations refute their claim that Defendants had "exclusive knowledge of a material fact." See Wolph v. Acer Am. Corp., No. C 09–01314 JSW, 2009 WL 2969467, at *4 (N.D. Cal. Sept. 14, 2009) ("[b]ased on Plaintiff['s] own allegations, Plaintiff [has] not alleged facts that show [Defendants] had exclusive knowledge of the [omitted] material facts and that Plaintiff[ ] could not have reasonably discovered such facts."); Stickrath v. Globalstar, Inc., No. C07–1941 THE,

2008 WL 344209, at *4 (N.D. Cal. Feb. 6, 2008) (allegation in complaint do not appear to support an allegation of exclusivity since Plaintiffs allege disclosure by Defendant "in public filings" and in "an application with the FCC"). Therefore, Plaintiffs fails to assert a duty to disclose based on exclusive knowledge of a material fact.

In addition, as to Plaintiffs' allegation that Defendants actively concealed material facts from them, Plaintiff must allege specific "affirmative acts on the part of the [D]efendants in hiding, concealing or covering up the matters complained of." Herron v. Best Buy Co. Inc., 924 F. Supp. 2d 1161, 1176 (E.D. Cal. 2013) (quoting Lingsch v. Savage, 213 Cal. App. 2d 729 734 (1963)). As with exclusive knowledge, "generalized allegations with respect to . . . active concealment" will not do. Id. (citing Hovsepian v. Apple, Inc., No. 08-5788 JF (PVT), 2009 WL 5069144, at *3 (N.D. Cal. Dec. 17, 2009).

Here, Plaintiffs make general conclusory allegations of active concealment, (Dkt. No. 1, Compl. ¶¶ 50, 120), without specific facts that Defendants actively tried to conceal the discrepant results; therefore, Plaintiffs have failed to assert a duty to disclose based on active concealment. See Herron, 924 F. Supp. 2d at 1176 (granting motion to dismiss on active concealment allegation based on general assertion that defendants "actively concealed material facts from Plaintiff and the Class.")

Because Plaintiffs have failed to assert a duty to disclose, the Court GRANTS Defendants' motion to dismiss under Rule 9(b) all causes of action premised on fraudulent omission.

D. Unjust Enrichment

Unjust enrichment is not a cause of action but a "principle underlying various doctrines and remedies, including quasi-contract." Jogani v. Superior Court, 165 Cal. App. 4th 901, 911 (2008). A claim for unjust enrichment cannot stand alone as an independent claim for relief. See Oestreicher v. Alienware Corp., 544 F. Supp. 2d 964, 975 (N.D. Cal. 2008) ("since plaintiff's fraud-based claims have been dismissed, plaintiff has no basis for its unjust enrichment claim."); Sanders v. Apple Inc., 672 F.

Supp. 2d 978, 989 (N.D. Cal. 2009) ("[unjust enrichment] claim will depend upon the viability of the Plaintiffs' other claims.").

In this case, since Plaintiffs have failed to allege a cause of action for relief, the unjust enrichment claim also must be dismissed.

E. Learned Intermediary Doctrine

In their moving papers, in describing that medical devices are not typical consumer products, Defendants raise the learned intermediary doctrine asserting that a manufacturer's duty to warn runs to the physician and not the patient but does not explain which cause of action is deficient based on this doctrine. In opposition, Plaintiffs notes the deficiency in Defendants' argument and further argue that if the learned intermediary doctrine applied, it is a fact-based defense to be determined at summary judgment or at trial and they also argue that the doctrine does not apply because INRatio products are not exclusively prescription devices and can be bought without a prescription.

California applies the "learned intermediary" doctrine which provides that the duty to warn in the case of medical devices runs to the physician, not the patient. Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 (1992) (prescription implanted medical device case); see also Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996). A manufacturer fulfills its duty to warn if it provides adequate warnings to the physician. Plenger, 11 Cal. App. 4th at 362 n. 6 (citing cases); see also Brown v. Superior Court, 44 Cal.3d 1049, 1062 n. 9 (1998). In order to prove causation, a plaintiff must allege that the inadequate warning or lack of warning about the medical device risk would have altered the prescribing physician's decision to use the product. Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) ("[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician."). Plaintiffs must also show that the failure to warn caused their injuries. Motus, 196 F. Supp. 2 at 991.

One district court has held that the learned intermediary doctrine applies to state consumer protections laws, such as the CLRA and UCL, but only if the claims are predicated on a failure to warn. Saavedra v. Eli Lilly and Co., No. 12cv9366-SVW-MAN, 2013WL 3148923, at *3-4 (C.D. Cal. June 13, 2013). As one district court in Texas noted,

> The gravamen of all of Plaintiffs' causes of action, including misrepresentation and violation of [Texas's Deceptive Trade Practices Act, "DTPA"], is that [the defendant drug manufacturer] failed to adequately warn of or disclose the severity of Norplant's side effects. Therefore, the learned intermediary doctrine applies to all of Plaintiffs' causes of action. Additionally, whether the failure to warn is couched as an affirmative misrepresentation or a misrepresentation by concealment, the allegation collapses into a charge that the drug manufacturer failed to warn. If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the DTPA or a claim for misrepresentation, then the doctrine would be rendered meaningless.

In re Norplant Contraceptive Prods. Liability Litigation, 955 F. Supp. 700, 709 (E.D. Tex. 1997).

Here, the Complaint does not assert a failure to warn cause of action; however, it appears that the misrepresentations and omissions claims are based on a failure to warn of the INRatio products' discrepant results. Plaintiffs argue, but do not allege in the complaint, that Andren purchased the INRatio2 testing kit at a pharmacy and therefore, the doctrine does not apply. Given that Plaintiffs are granted leave to amend, they should clarify whether the INRatio2 was prescribed by Andren's doctor or not. If INRatio2 was prescribed by a physician, then the doctrine applies to their case[5] and if so, Plaintiffs must properly allege a failure to warn Plaintiffs' prescribing physician in an amended complaint. See Tapia v. Davol, Inc., 116 F. Supp. 3d 1149, 1159 (S.D. Cal. 2015) (granting motion to dismiss failure to warn cause of action because the plaintiff failed to allege that the defendants failed to warn his prescribing physician but only alleged "physician" in general); see Buckely v. Align Tech, Inc., No. 13cv2812-

[5]Nonetheless, it would appear that the learned intermediary doctrine would apply as to Plaintiff Bludman because Plaintiffs do not argue that he purchased his INRatio2 PT/INR testing kit at a pharmacy.

EJD, 2015 WL 5698751, at *4 (N.D. Cal. Sept. 29, 2015) (to the extent the plaintiff alleges a failure to warn, those claims fail due to the failure to allege that her dentist was misled by the defendant).

F. Leave to Amend

Leave to amend, whether or not requested by the plaintiff, should be granted unless amendment would be futile. Schreiber Distrib. Co., 806 F.2d at 1401. While Plaintiffs do not seek leave to amend, the Court concludes that it would not be futile to allow leave to amend and GRANTS Plaintiffs' leave to amend their complaint. See id.

Conclusion

Based on the above, the Court GRANTS Defendants' motion to dismiss with leave to amend. If Plaintiffs seek to amend the complaint, they shall file an amended complaint within 20 days of the filing date of this order. If Plaintiffs do not seek to file an amended complaint, they shall file a notice of voluntary dismissal within 20 days of the filing date of this order. The hearing date set for September 16, 2016 shall be **vacated.**

IT IS SO ORDERED.

DATED: September 13, 2016

HON. GONZALO P. CURIEL
United States District Judge